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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/162,648 09/29/98 HISERODT

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EXAMINER

HM22/0716

MEYER PHARMACEUTICALS LLC
1761 KAISER AVENUE
IRVINE CA 92614

CHEN, S

ART UNIT

PAPER NUMBER

1633

DATE MAILED:

17
07/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/162,648

Applicant(s)

HISERQDT, JOHN C.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

Applicants amendment filed 4-30-01 has been entered. Claims 1 and 12 have been amended.

Claims 1-20 are pending and under consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 1-10, 12-16 and 18-20 remain rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Granger (US Patent 5,837,233).

Applicant argues that (a) loss of effectiveness at the end of a long period of time suggests that another type of cancer treatment should be substituted instead, (b) Granger teaches alloactivated cells are planted into the tumor bed at the time the primary tumor is removed by surgery, (c) the present application directs the clinician to consider administering a second dose

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of alloactivated cells into the tumor bed well before there is evidence of failure of the first dose, and (d) synergistic effect is obtained by administering two doses of allogeneic cells into the tumor bed (amendment, page 6-7). This is not found persuasive because Granger does teach more than one dose of the alloactivated cell could be administered to tumor site and Granger does teach intralesional implant of MLC cells for the patients with incurable, untreatable pancreatic cancer (e.g. column 11, lines 40-53). Granger teaches that "In accordance with conventional prudent formulating practices, a dosage near the lower end of the useful range may be employed initially and the dosage increased or decreased as indicated from the observed response, as in the routine procedure of the physician". Therefore, Granger does teach more than one dose of the alloactivated cell could be administered to tumor site and better effect than one dose administration could be obtained with reasonable expectation of success. Thus, claims remain rejected for the reasons set forth above and the reasons of record.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(f) he did not himself invent the subject matter sought to be patented.

5. Claims 1-8, 12-14 and 18-20 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

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Hiserodt, J. (the inventor of the present application) and Granger, G. (The inventor of US Patent 5,837,233) are the coauthors of the PCT publication WO 98/16238 that was published 4-23-98. The PCT publication teaches a method for stimulating an anti-tumor immunological response or treating a neoplastic disease in a human comprising mixing ex vivo a first cell population comprising tumor cells, and a second cell population comprising lymphocytes allogeneic to the lymphocytes, to produce a cell mixture, and administering an effective amount of the cell mixture to the human (e.g. page 58-59). The PCT publication also teaches that additional doses may be given, such as on a monthly or weekly basis, until the desired effect is achieved (e.g. page 27). The subject matter disclosed by the PCT publication is identical to what is claimed in claims 1-8, 12-14 and 18-20. It is unclear who is the inventor for the subject matter claimed in claims 1-8, 12-14 and 18-20.

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 11 and 17 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Granger (US Patent 5,837,233) as applied to claims 1-10, 12-16 and 18-20 above, and further in view of Feldhaus et al. (US Patent 5,759,805) and Haugland (1992)..

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Applicant argues the prior art Granger for 102/103 rejection has been overcome, and thus the 103 rejection does not stand. This is not found persuasive because of the reasons set forth above and the reasons of record.

8. Claims 1, 2, 6-8 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kruse et al., 1994 (IDS-Ref. 18, Journal of Neuro-Oncology, 19: 161-168).

Claims 1, 2, 6-8 and 12 are directed to a method for treating cancer, such as melanoma, pancreatic cancer, liver cancer, colon cancer, prostate cancer, and breast cancer, in a human patient comprising implanting at or around the site of a tumor in the patient a first and a second cell populations containing alloactivated lymphocytes that are allogeneic to leukocytes in the patient, and the administration of the first and second cell populations is at an interval of at least three days, about one and eight weeks, or about two and twelve months.

Kruse teaches single source or multiple sources allogeneic cytotoxic T lymphocytes (CTLs) were intracranially administered single time or multiple times to rat 9L gliosarcoma and shows lack of toxicity of allogeneic CTLs to the rat, and reduces or cures tumor burden in the rat 9L gliosarcoma model (e.g. summary). Kruse discloses that multiple administration of immune cells are more effective in lysing tumor cells than single administration in the *in vivo* rat experiment (e.g. page 162, right column). Kruse reports an increase in the survival time of 9L tumor-bearing rats given multiple infusions with multiple source allogeneic CTLs, and the study suggests that this may be similarly successful in the human (e.g. page 166, left column). The

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multiple administrations of the allogeneic CTLs were administered at 7, 10, 13, and 17 days after 500 9L tumor cells were intracranially infused into rat (e.g. page 163, Figure 1).

Kruse does not teach the administration interval at about one and eight weeks, or about two and twelve months.

It would have been obvious for one of ordinary skill at the time of the invention to apply the method taught by Kruse for treating cancer in human because of the suggestion of Kruse that this method may be similarly successful in the human and that it is successful in treating tumor cells in rat. It would have been obvious for one of ordinary skill at the time of the invention to use different interval times of allogeneic CTLs administration because different interval times of administration are routine optimization of variables for obtaining better effects of the allogeneic CTLs.

One of ordinary skill at the time the invention was made would have been motivated to practice the claimed invention in order to reduce or cure tumor cell burden in the human so as to provide a therapeutic method for treating human cancers. Thus, claims 1, 2, 6-8 and 12 are rejected under 35 U.S.C. 103(a).

Conclusion

No claim is allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (703) 305-1678. The examiner can normally be reached on Monday to Friday from 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached on (703) 305-4051. The fax phone number for this group is (703) 308-4242.

Questions of formal matters can be directed to the patent analyst, Kimberly Davis, whose telephone number is (703) 305-3015.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Shin-Lin Chen, Ph.D.


DEBORAH J. R. CLARK
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1800